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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,703	03/26/2001	Alexander Straub	LEA-33-187	3269

7590 12/24/2002

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EXAMINER
FORD, JOHN M

ART UNIT	PAPER NUMBER
1624	10

DATE MAILED: 12/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/744703	Straub
Examiner	**Group Art Unit**
J. M. Ford	1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on Oct 7, 2002.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1—9, 10, 11 and 13—21 is/are pending in the application.

Of the above claim(s) 7, 10 and 21 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1—5, 8, 10, 11, is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claim(s) 6, 13—17, 19 and 20 are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)–(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)–(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO–1449, Paper No(s). _____

☐ Interview Summary, PTO–413

☐ Notice of Reference(s) Cited, PTO–892

☐ Notice of Informal Patent Application, PTO–152

☐ Notice of Draftsperson's Patent Drawing Review, PTO–948

☐ Other _____

Office Action Summary

Applicants response of Oct. 7, 2002 is noted.

The claims in the application are claims 1--8, 10, 11 and 13--21.

Ms Truong is not available to work on this application. This application has been transferred to Senior Examiner John M. Ford.

Claim 6 is multiple processes in one claim. Lack of Unity of Invention in 371 cases provides that applicants may have one process examined with the compound claims. See 37 CFR 1.475.

Applicants heterocyclic expressions in claim 1 are rejected under 35 U.S.C. 112, 2nd paragraph.

Line 1 of claim 1 should read: A compound of the formula (I):

Substituted, derivatives and general are not acceptable terms. In the middle of page 89 one finds a 5 or 6 membered ring having up to 3 heteroatoms from O, S & N. The number of combinations of the heteroatoms is huge. Many variations of thiazines and oxazines coming out in the classification system before the pyrimidine of formula 1. A search would have to be done in class 544 in most of the subclasses before sub 310 for compounds that applicants have not demonstrated they even made, yet are claimed here. Adjacent O/S, S/S and O/O combinations are notoriously unstable.

Similarly, in the middle of page, a 3 to 8 membered ring with 1 to 4 hetero atoms, but much worse, as it is open because of the use of the word "contain", which is open to the inclusion of further unknown hetero atoms, SO and SO2 are not hetero atoms, 1 to 4 hetero atoms in 7 and (they are groups)

8 membered rings would all have to be conceived of by the reader and searched here; hundreds of subclasses.

Same, R6 in the middle of page 91 could not be allowed, and R9 and R10 in the middle of page 92. This time including the bald face "heterocyclyl."

Claim 1 is huge, the last species of page 93 is a carbohydrate in class 536, with no apparent antecedent basis. No antecedent basis can be found for the top species of page 94.

The heterocyclic language at the top of page 95 is the type that was rejected as unclear in In re Wiggins, 179 USPQ 421 at 423 (CCPA 1973), one does not know where the hetero atoms are in the ring. Each combination is a separate, classification and search as each ring is patentably distinct from the other.

It is not known what the heterocycle is in the last three lines of page 95.

A is rejected, as above, on page 96.

Claim 1 is rejected under 35 U.S.C. 112, 2nd and 1st paragraph. What is intended by the heterocyclic expressions? Where is adequate representative exemplification for a radical of the breadth of heterocyclic? We do not know where the hetero atoms are in the unknown ring.

The USPTO only recognizes: C,N,O,S,Se, or Te as atoms of a heterocyclic ring. Therefore, there is a need for applicants to indicate what they mean by heterocyclic.

Heterocyclic is not just a substituent; it is a whole body of art. Researchers often spend their entire life on hetero N heterocyclic compounds without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

What the heterocycle is, may often control the classification and search of the molecule.

The heterocyclic expressions are not acceptable, as they read on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the starting materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heteroaryl ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic reasons for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim; this ground finds its basis in second paragraph of section 112; second is that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matter embraced by the claim. The heterocyclic concept is

so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 12, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open, which ones: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2 or 1,3 or 1,4 or 1,2,4 or 1,3,4, etc., as each is a different entity, with a separate search.

These are compound claims, one must clearly know what is being claimed.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms? Not every expression says.

The heterocyclic term is not set forth in clear, specific language. The reader must produce the heterocyclic ring, in question.

It becomes necessary for applicants to indicate in the claims what they mean by heterocycle. Heterocyclic, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification. Not a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of 1--3 or 1--4 or 1--5 hetero atoms, in any combination, in multiple size rings is quire large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of heterocycle produces many different heterocyclic rings that could easily affect results.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expressions in claim 1 ~~is~~ are not acceptable, as ~~does~~ they not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting material for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

Why? Because that compound claim precludes others from making, using, or selling that compound for 17/20 years. Therefore, one must know what compound is being claimed.

The claims measure the invention, United Carbon Co. Vs. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. Vs. United States, 193 U.S.P.Q. 449, Claims measures the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 Held "that invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim". In re Priest, 199 U.S.P.Q. 1, at 15.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that stop the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The double patenting question will be revisited once we have allowable language in the claims.

Claim 2 is rejected for the reasons noted in the rejection of claim 1. See, lines 20 et seq. of page 98, and the bottom of page 99, and lines 21 et seq. of page 100.

It is not known what fused phenyl means on page 104, line 7.

Claim 3 is rejected for the reasons claim 1 was rejected. See the middle of page 105, and the top of page 106.

Line 1 of claim 4 should be: A compound according to claim 1.

What are the optional substituents in R1 of claim 4.

Claim 5 is rejected for the reasons claim 4 was rejected.

Accordingly claims 4 and 5 are rejected under 35 U.S.C. 112, 2nd paragraph.

One process need be elected from claim 6 under the provisions of 37 CFR 1.475 and PCT Rule 13.2. Failure to do so will result in claim 6 being held withdrawn under the provisions of MPEP 806.06 (f). Claim 6 demonstrate that the compounds, as claimed, may be made by more than one materially different process.

Claim 7 are amidines, in class 548, not the product of claim 1 and will have to be restricted out as they do not retain the pyrimidine identity of class 544.

Claims 8, 10 and 11 are not statutory as they are not written in proper method or composition form. Addition ingredient claims cannot be examined, here, as they would then not be the same scope as the final genus.

It could not be reasonable to consider all cardia vascular diseases, 37 CFR 1.475 and PCT Rule 13.2 make it clear that in addition to the elected single invention compounds that applicants may have one, clear, specific use of their compounds examined therewith. Applicants need to elect one such specific, demonstratable, World of Commerce disease from claims 13--17. Claim 17 is suggested.

Newly presented claims 19 and 20 are grouped with claim 6.

Claims 21 and 18 are addition ingredient claims and could not be examined here as they have additional ingredients that would keep them from being the same scope as claim 1.

The agreement to examine one method of use of the elected compounds, and one process of preparing the compounds, with the compounds, provides that they be of the same scope.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in Brenner v. Manson in, 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that Nelson v. Bowler, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419 is "whether the invention has

been brought to such perfection as to be capable of practice employment". This language is echoed in Bindra vs. Kelly, 206 USPQ 570.

MPEP 806.05 (h) provides for restriction. A broad disclosure of utility as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility".

The court focused on the fact that the applicant failed to identify a "specific utility" in Brenner v. Manson.

This requirement of one specific utility is consistent with Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT applications.

Therefore, applicants should limit the method claims to a "specific utility".

Examples of utility expressions that have been held to be insufficient are:

A disclosure that the claimed compounds can be used for "technical and pharmaceutical purpose" does not met the requirements of 35 U.S.C. 112. In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128.

The expressions "biological activity" and "biological properties" are too nebulous to meet the requirements of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F2d 936, 153 USPQ 48. Same, "good effects against a very wide range of insects". In re Lorenz et al. (CCPA 1962) 305 F2d 875, 134 USPQ 312.

The "how to use" requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds, if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted from their chemical structure, a disclosure that they possess a particular activity may not suffice as a description of how to use as required by 35 U.S.C. 112. In re Moureu et al. (CCPA 1965) 345 F2d 595, 145 USPQ 452.

Statements of Utility which relate to or imply the treatment of a disease are subject to closer scrutiny. Ex parte Moore et al. (POBA 1960) 128 USPQ 8. Thus, when the disclosed utility is the production of a physiological response, e.g., antidepressant effect, the dosage effective to achieve this response in a host, whether human or animal, must be disclosed. In re Garner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

This requirement of one specific utility is consistent with the Unity of Invention practice in International Applications and National Phase Applications under 35 U.S.C. 371.

Examples of terms and expressions that do not satisfy 35 U.S.C. 112, 1st paragraph, are statement that a product is a "pharmaceutical", "therapeutic agent", or has "biological utility", or is "an intermediate to make a drug", citing, respectively, In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Lorenz et al. (CCPA 1962) 305 F2d 875, 135 F2d 875, 135 USPQ 312

and Ex parte Brokmann et al. (POBA 1959) 127 USPQ 57; In re Kirk et al. (CCPA 1967) 153 USPQ 48; and In re Joly et al. (CCPA 1967) 376 F2d 906, 153 USPQ 45.

A specification which discloses only one mode of administration of a medicinal for the purpose of effecting a modification in a body function does not provide for a claim not directed to that specific mode. Ex parte Proctor (POBA 1966 158 USPQ 677).

A claim which designates the amount of an ingredient of a claimed composition as "an effective amount" is too broad and indefinite if it does not designate the intended effect. Ex parte Dobson et al. (POBA 1969) 165 USPQ 29. In re Fredriksen, 102 USPA 35, (CCPA 1954).

Issenstead v. Watson, (DCDC 1957) 269 F. Supp 630, 155 USPQ 838. Noted where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner Ferguson, (POBA 1957) 177 USPQ 229.

Where utility is based on the alleged enhancement of activity of known medicinals, the CCPA upheld the Examiner's requirement that the applicant submit evidence which substantiated the allegation, the Court holding such requirement proper where utility is based on that type of allegation, unless one skilled in the art would accept them as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F2d 924, 134 USPQ 335.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference

of human use the require proof thereof, when such use is a medical nature for the treatment of a serious disease. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Cittron. (CCPA et al.) 325 F2d 248, 139 USPQ 516; In parte Hartop et al., (CCPA 1962) 311 F2d 249, 135 USPQ 419.

The Supreme Court declined to express a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner , Comr. Pats. vs. Manson, (USSC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent be granted on a chemical compound, or a process for its production, whose sole "utility: consists of its potential role as an object of use-testing, reasoning the patent system is related to the world of commerce rather than the realm of philosophy ibid., 148 USPQ at 696.

Assay tests or laboratory screen test are not acceptable.

A Broad statement of utility, as in the cited claims cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

All cardia vascular diseases cannot be considered one use of their compounds.

The U.S. PTO has amended the guidelines to clarity "specific utility.". The focus was on Brenner v. Manson. The utility need be one in the real World of Commerce.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by the American Medical Association Council on Pharmacy, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123

USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven types of cancer with a member of a class of several compounds. In re Buting, (CCPA 1969) 418 F2d 540, 163 USPQ 689.

John M. Ford:jmr

December 19, 2002

JOHN M. FORD
PRIMARY EXAMINER